

REMARKS/ARGUMENTS

Reconsideration of the present application in view of above amendments and the following remarks is requested.

I. Status of the claims

Claims 11, 12, 22, 23, 26-29, and 31-33 are currently pending. Claims 11 and 27 have been amended to specifically recite diisopropylether and diethylether as ether solvents. Support for these amendments can be found in the published specification at, for example, ¶¶47, 65, and 70. Claims 26 and 31 have additionally been amended to remove the phrase “in which atorvastatin calcium is not soluble or is poorly soluble.” Claims 32 and 33 were previously withdrawn pursuant to a Restriction Requirement. Applicants reserve their right to pursue the subject matter of those claims in one or more divisional applications. No new matter has been added by way of this response.

II. Enablement rejection

Claims 11, 12, 22, 23, 26-29, and 31-33 stand rejected under 35 U.S.C. §112, 1st paragraph, for lack of enablement. Specifically, the Examiner maintains that the field of making crystalline/amorphous forms of atorvastatin is unpredictable, and that undue experimentation would be required for one of ordinary skill in the art to determine which solvents would lead to amorphous atorvastatin. The Examiner also suggests narrowing the scope of claims to diisopropyl ether.

Applicants respectfully disagree with the Examiner’s reasoning. However, without acquiescing to the validity of the Examiner’s rejection, and solely for the purpose of advancing prosecution, Applicants have amended the claims to specifically recite diisopropyl ether and diethylether as the ether solvents in which amorphous atorvastatin calcium is poorly soluble or insoluble. The Examiner has conceded that the claims are enabled for diisopropyl ether. Applicants submit that diethylether is also enabled because it is used in a washing step following the precipitation of amorphous atorvastatin calcium – a step that requires a solvent in which the precipitated amorphous atorvastatin is insoluble. *See* Examples 4 and 5. Thus, Applicants

respectfully submit that the specification makes clear that diethylether embodies the requisite properties necessary to precipitate atorvastatin calcium using the claimed process (i.e., it is a solvent in which atorvastatin is not soluble or is sparingly soluble). Applicants reserve their right to file a continuation application to pursue the full class of ether solvents.

Given the foregoing, Applicants submit that the claims are fully enabled. Accordingly, Applicants respectfully request that the enablement rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, all pending claims are believed to be allowable and the application is in condition for allowance. Therefore, a Notice of Allowance is respectfully requested. Should the Examiner have any further issues regarding this application, the Examiner is requested to contact the undersigned attorney for the applicant at the telephone number provided below.

P.O. Box 2903
Minneapolis, MN 55402-0903
206.342.6200

Respectfully submitted,
MERCHANT & GOULD P.C.

/Christopher L. Frank/
Christopher L. Frank
Reg. No. 67,326
Direct Dial 206.342.6255

